REMARKS

Claims 1, 2 and 5-21 are pending in this application. Claim 21 is withdrawn. No claim is allowed. Claim 1 is amended herein to address the definiteness issue raised by the Examiner. No new matter is added by way of these amendments. Applicants respectfully request entry of the claim amendments and reconsideration in view of the following remarks.

Applicants respectfully point out that the present response addresses the issues of record and so is intended to advance prosecution and resolve issues of record without introduction of new issues requiring additional search or consideration. Additionally, the present response addresses issues raised for the first time in the Action mailed February 8, 2008 and so could not have been previously presented. Therefore, the instant response should be considered in full with Applicants' request for reconsideration.

Premature finality

Applicants respectfully point out that the Action mailed February 8, 2008 is the first Action on the merits following the filing of a Notice of Appeal on July 26, 2007 (which closed prosecution) and a Request for Continued Examination (RCE) on October 26, 2007 (which re-opened prosecution). Additionally, the Action includes two new rejections, under 35 U.S.C. § 112, which have not been previously asserted. These new rejections clearly demonstrate that the claims were not rejected solely for the reasons of record in the previous Action mailed January 26, 2007.

Therefore, the assertion of "final" status in the Action mailed February 8, 2008 is premature because the claims have not been twice rejected following the RCE. Reconsideration and withdrawal of "finality" is respectfully requested.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1, 2 and 5-20 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserts that while there is support for a lesion having an occult component of $\geq$50% to $\leq$100%, there is

allegedly no support in the originally filed disclosure for >50% to <100%. Applicants respectfully traverse the rejection.

"To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." *See, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). MPEP § 2163(I).

Applicants respectfully submit that a person of skill in the art would clearly understand the symbols (≥ and ≤) as used in the specification to provide written descriptive support for the pending claims. For example, ≥50% (i.e., "greater than or equal to 50%") explicitly provides written description for >50% (i.e., "greater than 50%"). Similarly, ≤100% (i.e., "less than or equal to 100%") provides explicit support for <100% (i.e., "less than 100%"). This interpretation of the terms is necessarily correct because it is certain that the symbols used (≥ and ≤) are distinct from both the equal sign and the symbols > and < used to indicate "greater than" and "less than", respectively.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 1, 2 and 5-20 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Specifically, the Examiner asserts that the limitation in claim 1 of "or both (a) and (b)" renders the claim indefinite because no alternative language is provide for (a) and (b). Applicants respectfully traverse the rejection.

As previously presented, claim 1 listed a series of conditions beginning with "(a)" where the series was clearly linked by "or" as a conjunction. Therefore, a skilled person would readily understand that the series of conditions were related in the alternative such that the individual conditions in the series are (a) or (b) or both (a) and (b). The instant rejection offers no alternative interpretation that would give rise to an issue of indefiniteness.

Nevertheless, solely in the interest of advancing prosecution in the instant application, claim 1 is amended herein to clarify that the subject is assessed as having either (a) or (b), or both (a) and (b), consistent with the interpretation applied by the Examiner.

Applicants respectfully submit that the claims, as amended, are clear and definite. Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

Rejection Under 35 U.S.C. § 103(a)

Claims 1, 2, 5-12, 14-18 and 20 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the TAP Report 1, *Arch. Ophthalmol.* 117:1329-45 (1999) (hereinafter "TAP Report 1"). Claims 13 and 19 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the TAP Report 1 in view of Zeimer (U.S. 5,935,942). Applicants traverse the rejections for reasons of record, as well as at least the following.

The Examiner contends that the treatment group described in the TAP Report 1 included 302 patients[1] whose lesions included evidence of occult CNV, as well as at least 199 patients having visual acuity less than 53 letters prior to treatment (see TAP Report 1, Table 2 at page 1334). Thus, the Examiner asserts that there must necessarily have been overlap between these two groups, such that at least about 100 patients having evidence of *some* occult CNV and poor visual acuity received PDT with verteporfin. In addition, the Examiner contends that certain patients in the

[1] Applicants note that only 201 patients in the verteporfin treatment group are reported to have a lesion composed of >0 to <50% classic CNV (i.e., >50 to < 100% occult CNV). *See* TAP Report 1, Table 2, at page 1334.

verteporfin treatment group had small lesions of less than 6 disc areas (see TAP Report 1, Table 2 at page 1335), and therefore states that "the population who showed Occult CNV in the TAP Report and further received verteporfin, are the same as the instantly claimed population." *See* Office action at page 5. Thus, the Examiner concludes that "the instantly claimed intended purpose is inherently achieved." *Id.* Applicants respectfully disagree.

The Examiner appears to be arguing that the claimed subgroup is inherently somewhere in the verteporfin-treatment population, because data for each of the three parameters *assessed separately* is presented in the TAP Report 1. Applicants respectfully submit that because certain patients having poor visual acuity and/or small lesion size also have *some* evidence of occult CNV does not *necessarily* mean that such patients fell within the scope of the claims, which require that the occult component be >50% and <100% of the lesion and that the subject have small lesion size, or poor visual acuity prior to treatment, or both.

Moreover, the Examiner's conclusion ignores the express teachings of the TAP Report 1 that occult lesions, and particularly lesions having between >50% and <100% occult character, are non-responsive to PDT treatment with verteporfin.

The authors expressly state this outcome at least three times:

> "With respect to eyes with evidence of occult CNV at study entry, **no major differences** were noted between the verteporfin and placebo groups based on angiogenic outcomes of occult CNV." *See* TAP Report 1, page 1337, col. 2 (emphasis added).

> "**No appreciable difference** was observed in the group of patients with lesions in which the area of classic CNV was greater than 0% but less than 50% of the area of the entire lesion at baseline." *See* TAP Report 1, page 1339, col. 2 (emphasis added).

> "[L]esions in which the area of classic CNV was greater than 0% but less than 50% of the area of the entire lesion at baseline had **no visual acuity benefit** with treatment (i.e., no difference in the proportion of cases with a loss of ≥15 letters). Even after adjustment for possibly confounding effects of several baseline covariates… the relationship remained for the baseline lesion components." *See* TAP Report 1, page 1341, col. 2 (emphasis added).

In spite of these repeated, express statements by the study's authors, the Examiner asserts that it would have been obvious to one of ordinary skill in the art to treat patients with occult CNV lesions having an occult component of >50% to <100%. The Examiner acknowledges that the results in Table 5 show no benefit for verteporfin therapy in patients with >0 to <50% classic CNV (i.e., >50% to <100% occult CNV). *See* Office action at page 8. Nevertheless, the Examiner asserts that because of the benefit to patients with ≥50% classic CNV (i.e., ≤50% occult CNV) and to patients with 0% classic CNV (i.e., 100% occult CNV), it would have been obvious with routine experimentation to treat patients having lesions with an occult component within the claimed range of >50% to <100% occult CNV. *Id.* In other words, the Examiner contends that it would have been "obvious to do" exactly what the authors of the cited document say doesn't work. Applicants must respectfully disagree.

Contrary to the assertions of the Examiner, a person of skill in the art would not have had a reasonable expectation of success that the instantly claimed methods would be effective, in view of the express teachings of the TAP Report 1 cited above, which clearly and unequivocally state that PDT treatment with verteporfin provided no visual acuity benefit and no appreciable difference from placebo for patients with lesions having an occult component of >50% to <100% occult CNV. The Examiner has simply provided no justification why one of skill in the art would disregard a major finding of the TAP Report 1 and attempt "routine experimentation" into the claimed range of >50% to <100% occult CNV, when the TAP Report 1 clearly teaches away from the treatment of such lesions with PDT.

Moreover, nothing in the TAP Report 1 suggests selecting the subgroup of patients having the combination of features in the instant claims, to arrive at the beneficial results. The TAP Report 1 discloses that patients with >50% and <100% occult lesions cannot be successfully treated with PDT using verteporfin. No guidance is provided that would lead one of skill in the art to select the claimed subgroup from within this set of patients for which PDT was ineffective, including the additional criteria of small lesion size, or poor visual acuity, or both, as in the instant claims. Therefore, the TAP Report 1 provides neither a reasonable expectation of success nor any motivation to practice the instantly claimed methods.

In view of the foregoing, Applicants respectfully submit that a *prima facie* case of obviousness has not been established based on the TAP Report 1. With respect to claims 13 and 19, nothing in Zeimer addresses the deficiencies in the Office's *prima facie* case noted above. Accordingly, Applicants respectfully submit that the instant claims are nonobvious over the TAP Report 1, alone or in combination with Zeimer. Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273012012500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 8, 2008

Respectfully submitted,

Electronic signature: /Leslie A. Robinson/
Leslie A. Robinson
Registration No.: 54,403
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
(858) 314-7692